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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/478,748	06/07/95	WALDMANN	T 2026-4003US3

WILLIAM S. FEILER, ESQ.  
MORGAN & FINNEGAN, L.L.P.  
345 PARK AVE.  
NEW YORK NY 10154

HM12/0609

EXAMINER

GAMBEL, F

ART UNIT	PAPER NUMBER
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1644

25

DATE MAILED:

06/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

08/478748

Applicant(s)

WALDMANN

Examiner

GAMBEL

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 3/26/99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 27 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 27 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

### DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Technology Center 1600.

2. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.129(a).

Applicant's second submission after final filed on 3/26/99 (Paper No. 24) has been entered.

3. Applicant's amendment, filed 3/26/99 (Paper No. 24) has been entered.

Claims 1-18 and 24-26 have been canceled. Claims 19-23 have been canceled previously.

Claim 27 has been added and being acted upon.

4. The text of those sections of Title 35 USC not included in this Action can be found in prior Actions.

This Office Action will be in response to applicant's arguments, filed 3/26/99 (Paper No. 24).

The rejections of record can be found in the previous Office Actions (Paper Nos. 7/9/12/17/20).

5. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see form PTO-948 previously sent in Paper No. 7.

Applicant is reminded to change the Brief Description of the Drawings in accordance with these changes (see 7. Views).

6. The priority date of the instant claimed limitations appears to be that of the instant application (6/7/95).

7. The examiner acknowledges that setting forth a claims as set forth in newly added claim 27 would distinguish itself from the previous claimed limitations by setting forth the determination step prior to the administration step. The examiner also acknowledged that such claimed limitations would be subject to consideration and would constitute patentable subject matter, provided the prior art did not meet this determination step of the claimed methods.

Applicant's arguments including the Waldmann declaration under 37 C.F.R. § 1.132 filed 3/2/99 (Paper Nos. 23/24) have been fully considered but are not found convincing in that Waldmann (Blood, 1993) appears to teach treating patients with yttrium-labeled anti-Tac antibody in the dosages ranges including the determination of soluble IL-2R levels, encompassed by the claimed methods (see next section). Applicant is invited to distinguish this reference from the instant claimed method.

8. Claim 27 is rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious Waldmann (Blood, 1993). Waldmann et al. teaches treating patients with yttrium-labeled anti-Tac antibody in the dosages ranges including the determination of soluble IL-2R levels, encompassed by the claimed methods (see entire document, including Materials and Methods such as the Therapeutic Study Plan, Results including Tables 1 and 2, Discussion). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced therapeutic modalities.

In the alternative, it would have obvious to give 20 mg of anti-Tac comprising 5-15 mCi yttrium to patients with sIL-2R levels of greater than 50,000 given the clinical results/duration of the different patients in these studies. From the teachings of the reference, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.  
Patent Examiner  
Group 1640  
Technology Center 1600  
June 3, 1999

*Phillip Gambel*

*Christina Chan*  
CHRISTINA Y. CHAN  
SUPERVISORY PATENT EXAMINER  
GROUP 1800-1640